

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P-0020	5717

7590 08/27/2003
Jeffrey C. Kelly, Esq.
Kensley Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 08/27/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/010,304

Applicant(s)

RINGEISEN, TIMOTHY

Examin r

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6, 9</u> . | 6) <input type="checkbox"/> Other: |

Art Unit: 1615

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Information Disclosure Statement

entered 6/2/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 20 recites the limitation "the porous polymer prosthesis" in line 1 of claim. There is insufficient antecedent basis for this limitation in the claim. The claim is dependent from claim 15, which does not mention a polymeric prosthesis.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 3, 11 – 13, 15, 17, 25 – 27, 29, 30 and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Reischl et al (USPN 3,553,008). The claims are drawn to a process for making a porous polymeric material comprising the steps of dissolving a polymer in a solvent

Art Unit: 1615

resulting in a solution; contacting the solution with a second solvent and forming a gel; shaping the resulting gel, and removing the solvents. The polymer can be polyurethane.

Reischl et al discloses a method for making a porous polymeric material. The process comprises dissolving polyurethane in a first solvent. A second solvent is added to the solution, providing that the polyurethane is miscible in it. The gel is placed onto a substrate and the solvents are removed through evaporation. Tetrahydrofuran is disclosed as a possible first solvent. The resultant gel mixture is shaped and the solvents are removed (Abstract; col. 1, lin. 54 – col. 2, lin. 25; col. 5, lin. 20 – 70; claim 1). These disclosures render the claims anticipated.

3. Claims 1, 2, 4, 12, 15 – 17, 25, 26, 29 and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Einstman et al (USPN 3,492,154). The claims are drawn to a process for making a porous polymeric material comprising the steps of dissolving a polymer in a solvent resulting in a solution; contacting the solution with a second solvent and forming a gel; shaping the resulting gel, and removing the solvents. The polymer can be polyurethane.

Einstman discloses a process for making a porous polymeric sheet of polyurethane. The process comprises adding a second solvent to a polyurethane solution. The second solvent is a non-solvent, which coagulates the solution. Chloroform is disclosed as the second non-solvent (Abstract; col. 5, lin. 3 – 47; col. 7, lin. 47 – 63; claim 1). These disclosures along with others render the claims anticipated.

4. Claims 1, 8, 10, 15, 16, 23, 24, 26, 27, 29, 31, and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al (USPN 5,077,049). The claims are drawn to a process for making a porous polymeric material comprising the steps of dissolving a polymer in a solvent resulting in a solution; contacting the solution with a second solvent and forming a gel; shaping

Art Unit: 1615

the resulting gel, and removing the solvents. The polymer can be polyurethane. The porous polymeric material further acts as a scaffold for a biologically active agent.

Dunn et al discloses a process for making a porous polymeric implant. The implant comprises biologically active agents such as growth hormones and the like (col. 6, lin. 51 – col. 7, lin. 2). Combining a polymer solution with a coagulating solvent forms the porous implant. The polymer solution comprises a biocompatible polymer dissolved in a solvent. The polymer can be polyurethane, and the second solvent can be dimethyl sulfoxide, or tetrahydrofuran (col. 5, lin. 7 – 51). The polymer/solvent/agent mixture is injected into the body where it continues to coagulate and takes on the shape of the implant site. The solvents permeate out of the polymeric body leaving pores (Ibid.) These disclosures along with others (examples, claims) render these claims anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1615

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 6, 7, 9, 11, 18 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Einstman et al (USPN 3,492,154) in view of Helmus et al (USPN 5,447,724) and Le Noane (USPN 4,769,286). The claims are drawn to a process for making a polymeric material where the polymer includes a biologically active agent. Also the polymeric material is contacted with various medical materials.

As discussed above Einstman discloses a porous polymeric material. The material is made of polyurethane and comprises the solvents of the instant claims. What is lacking is a disclosure of biological active or medical materials being contacted with the polymeric material of Einstman. Einstman suggests that the polymers of the invention can be used in combination with biological and supporting materials (col. 1, lin. 37 – 41). Also porous polymeric coatings are well known in the art of medical devices.

Helmus discloses medical devices where a surface comprises porous polymeric composition holding a biologically active compound (Abstract). The device can be in the form of a suture or any implantable medical device. The device can also aid in adhesion to the body. The polymeric coating, which contact the surface of the body, and releases the biological active agent, can be made of the polymers of the instant claims (col. 2, lin. 15 – 65).

Le Noane teaches reinforcing materials such as fibers, rings and other devices. The devices comprise porous polymers incorporated into the structure of the fibers (Abstract). The polymers for use in the materials of the reference are within the instant claims (claims).

With regard to claims 6, 7 and 9 which are drawn to the order in which the active agent is added to the polymeric compound, it is the position of the examiner that such limitations do not

Art Unit: 1615

carry patentable weight in light of the prior art. These limitations are well within the level of skill in the art, to manipulate and configure in order to achieve the best release of the active compounds. Barring a showing of criticality to the order in which the active agent is added, the claims will remain obviated in view of the prior art.

With these things in mind a skilled artisan would have been motivated to combine the porous polymer of Einstman with the implantable devices of Helmus or supporting structures of Le Noane. The porous polymer would have allowed for the release of active agents in Helmus and provided a supportive substrate for the threads, fibers and other devices of Le Noane. The porous polymer would aid in the adhesion of the implant of Helmus. A skilled artisan would expect the porous polymer to both support and be able to release active agents. It would have been obvious to combine the teachings with an expected result of a supportive, active-agent releasing device.

8. Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al (USPN 5,077,049) in combination with Reischl et al (USPN 3,553,008).

As discussed above Dunn et al discloses a process for making a porous polymer. The reference discloses various solvents including dimethyl sulfoxide (col. 5, lin. 37 – 51). The reference discloses a polymer/solvent/agent combination, which is gelled and has its solvent removed. What is lacking is a disclosure of the order in which the solvent is used. The polymer is presented in the form of a solution of dissolved polymer, where the second polymer acts as the gelling polymer. Tetrahydrofuran is well known as a dissolving polymer as seen in Reischl et al. Reischl discloses the solvent as a dissolving solvent for polyurethane. Dunn discloses dimethyl sulfoxide as a gelling second solvent. A skilled artisan would be motivated to combine the

Art Unit: 1615

solvents since both reference teach the creation of a porous polymer. The solvents used by both Dunn and Reischl are well known in the art of making porous polymers.

It would have been obvious to dissolve the polymer with the tetrahydrofuran of Reischl and further gel the polymer with solvents of Dunn. A skilled artisan would have been motivated to combine the teachings as such in order to insure the proper porosity of the resultant gelled polymer. A skilled artisan would expect gelled polymer capable of carrying active agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600